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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,620	02/04/2002	Sanna-Maria Kakonen	2328-123	2067

6449 7590 01/11/2005

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WASHINGTON, DC 20005

EXAMINER
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CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	Application No.	Applicant(s)
	09/937,620	KAKONEN ET AL.
Examiner	Art Unit	
Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 11/1/2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1,2,4,8-11,15,17 and 21-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1,2,4 and 8 is/are allowed.
- 6) Claim(s) 9-11, 15, 24-27 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

Applicant's amendment filed on 11/1/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 3, 5-7, 12-14, 16, 18-20 are cancelled.
2. Claims 21-27 are added to the instant application.
3. Currently, claims 1-2, 4, 8-11, 15, 17, 21-27 are under examination.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 9-11, 15, 24-27 rejected under 35 U.S.C. 102(a) as being anticipated by Hellman et al. (WO 99/09058).

Hellman et al. teach an immunoassay to measure gamma-carboxylated osteocalcin in a body fluid sample from patients. The immunoassay kit includes capturing reagents, such as recombinant monoclonal antibody or recombinant antibody fragment for gamma-carboxylated osteocalcin, and EDTA for eliminating bivalent ions, e.g. Ca++ (See page 2, line 12-25; Table 2; Table 3-5). The antibody can recognize epitopes occurring in the region of amino acids 17-24 of the gamma-carboxylated osteocalcin molecule (See Abstract, claim 5). The kit is for use of investigating bone disorders, fragility, fracture or osteoporosis (See Abstract).

With respect to claim 10, Hellman et al. teach various monoclonal antibodies in two-sites immunoassay to determine the intact osteocalcin (OC) and the total OC (See Table 2).

With respect to claim 11 and 24, Hellman et al. teach an antibody having the specific epitopes, e.g. 17-24, to determine the gamma-carboxylated osteocalcin (See claim 5).

With respect to claim 15, 25-27, the antibody taught by Hellman is made by recombination technique (See Method and Materials).

***Response to Applicant's Arguments***

3. The "Scope of Enablement" rejection under 35 USC §112, first paragraph set forth in the previous Office Action is withdrawn.
4. Applicant's arguments with respect to claims 9-20 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

5. Claims 1-2, 4, 8 are allowed.
6. The following is an examiner's statement of reasons for allowance: no prior art teaches or fairly suggests using gamma-carboxylated osteocalcin (COC) or the ratio of total or intact osteocalcin (TOC or IOC) to COC, i.e. COC/IOC or COC/TOC, as an assessment of bone fracture, fragility or osteoporosis.
7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu  
Examiner

Art Unit 1641

January 5, 2005

LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
01/07/05